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# PART 1. OVERVIEW INFORMATION

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

Federal Agency Name: Federal Centers for Disease Control and Prevention (CDC)

**Funding Opportunity Title:** 

Patient Protection and Affordable Care Act

Epidemiology and Laboratory Capacity for Infectious Diseases (ELC)

Building and Strengthening Epidemiology, Laboratory and Health Information Systems

Capacity in State and Local Health Departments

**Announcement Type:** Continuation – Type 5

Agency Funding Opportunity Number: CDC-RFA-CI10–101202PPHF11

Catalog of Federal Domestic Assistance Number: 93.521

**Key Dates:** 

Application Deadline Date: May 2, 2011; 5:00pm Eastern Standard Time

**Additional Overview Content:** 

This Announcement represents the 2<sup>nd</sup> year continuation solicitation for existing ELC recipients to continue and expand their Affordable Care Act (ACA) activities initiated in 2010 under Funding Opportunity Announcement # CI10-1012.

Measurable outcomes of the program will be in alignment with one (or more) of the following performance goal(s) for the National Center for Emerging and Zoonotic Infectious Diseases: Protect Americans from Infectious Disease; and the Office for Surveillance, Epidemiology and Laboratory Services: Enhance and Maintain Innovative Public Health Surveillance Systems.

This announcement is only for non-research activities supported by CDC. If research is proposed, the application will not be reviewed. For the definition of research, please see the CDC Web site at the following Internet address:

http://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf.

# PART 2. FULL TEXT

# I. FUNDING OPPORTUNITY DESCRIPTION

## **Statutory Authority**

Public Health Service Act Sections 301(a) [42 U.S.C. 241(a)] and 317(k) (2) [42 U.S.C. 247b (k) (2)], as amended and the Patient Protection and Affordable Care Act (PL 111-148), Title IV, Sections 4002 and 4304 (Prevention and Public Health Fund).

# Background

On March 23, 2010, the President signed into law the Patient Protection and Affordable Care Act (the Affordable Care Act). The Affordable Care Act is designed to improve and expand the scope of health care coverage for Americans. Cost savings through disease prevention is an important element of this legislation, and the Affordable Care Act has established a Prevention and Public Health Fund (PPHF) for this purpose. Specifically, the legislation states in Section 4002 that the PPHF is to "provide for expanded and sustained national investment in prevention and public health programs to improve health and help restrain the rate of growth in private and public sector health care costs." A number of CDC programs have been implemented in response to the ACA, including programs aimed at building public health infrastructure that will help state and local health departments meet 21st century challenges. These infrastructure building programs include ELC ACA (the subject of this FOA) as well as programs to train/develop the public health workforce and the National Public Health Improvement Initiative (NPHII) managed by the Office for State, Tribal, Local and Territorial Support, which aims to

systematically increase the performance management capacity of public health departments in order to ensure that public health goals are effectively and efficiently met (see http://www.cdc.gov/ostlts/nphii/index.html).

This announcement implements second year continuation and expansion ACA funding for the Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) program and continues to build upon ELC's investment in infrastructure in state and local health departments

The ELC program was initiated in 1995 as one of the first key activities under CDC's plan to address emerging infectious disease threats. Starting out as limited funding for a small number of states, the program has grown to become one of CDC's key nationwide cooperative agreements for supporting state and local capacity including both 1) crosscutting, flexible surveillance, epidemiology, and laboratory capacity and health information systems capacity which serve infectious diseases and all other public health threats, as well as 2) infectious disease-area specific activities (e.g., foodborne diseases, influenza, antimicrobial resistance, etc.). The overall purpose of the ELC cooperative agreement program is to assist state public health agencies improve surveillance for, and response to, infectious diseases and other public health threats by (1) strengthening epidemiologic capacity; (2) enhancing laboratory practice; (3) improving information systems; and (4) developing and implementing prevention and control strategies.

Capacity built and sustained by the ELC helps prevent disease through enhanced surveillance of known and emerging infectious diseases and other public health threats,

leading to more rapid response to disease outbreaks and better development, implementation and evaluation of public health interventions.

### Purpose

The purpose of this Affordable Care Act funding for ELC is to enhance public health programs to improve health and help restrain the rate of growth of health care costs through building epidemiology, laboratory, and health information systems capacity in state and local public health departments. In FY2011, the specific aim is to 1) sustain key activities initiated in the FY2010 awards, 2) advance national implementation of electronic laboratory reporting (ELR), 3) to build or support syndromic surveillance capability at the state or local level and to enable health departments to participate in CDC's BioSense Program, 4) to build prevention and control capacity in healthcare associated infections (HAI) and 5) to conduct surveillance and effectiveness activities for vaccine preventable diseases.

This guidance addresses the following four inter-related areas which are fully consistent with and build upon the existing ELC activities:

- a) Epidemiology Capacity To ensure staff are well-trained and well-equipped to identify, characterize, and provide rapid, effective, and flexible response to infectious disease threats.
- b) Laboratory Capacity To achieve modern and well-equipped public health laboratories, with well-trained staff, employing high quality laboratory processes

- and systems that foster communication and appropriate integration between laboratory and epidemiology functions.
- c) Health Information Systems Capacity To develop and enhance current health information infrastructure for public health agencies. Working towards modern, standards-based and interoperable systems that support electronic exchange of information within and between epidemiology and laboratory functions in public health agencies (e.g., systems that support public health surveillance and investigation, laboratory information management systems (LIMS)); among local, state, and federal public health agencies; and between public health agencies and clinical care systems (e.g., health care providers, hospital emergency departments, clinical laboratories). A main emphasis of this FOA is to advance national implementation of ELR, including support for states to accept and work with incoming ELR messages in their surveillance systems and to develop and implement capacity to handle messages according to Meaningful Use (MU) standards. The Health Information Technology for Economic and Clinical Health (HITECH) Act MU<sup>1</sup> incentives and standards for healthcare providers create a vital opportunity to enhance the receipt of electronic reports of reportable laboratory results and syndromic surveillance event reports, and to communicate public health laboratory results to clinicians via their electronic health record systems. An important objective of this funding opportunity is to support states to

<sup>&</sup>lt;sup>1</sup> Officially known as the Department of Health and Human Services (HHS), Centers for Medicaid and Medicare Services (CMS) Electronic Health Record Incentive Program and associated HHS Office of the National Coordinator for HIT standards. Further information available at <a href="www.cdc.gov/osels/phitpo/mu/">www.cdc.gov/osels/phitpo/mu/</a> and

http://healthit.hhs.gov/portal/server.pt/community/healthit hhs gov meaningful use announcement/2996 Relevant regulations are at <a href="http://edocket.access.gpo.gov/2010/pdf/2010-17207.pdf">http://edocket.access.gpo.gov/2010/pdf/2010-17207.pdf</a> and http://edocket.access.gpo.gov/2010/pdf/2010-17210.pdf)

address challenges and opportunities created by the MU program; however, this funding opportunity is not intended to interrupt or undermine current successful ELR transmissions, even if those transmissions do not yet conform to standards for MU.

d) Targeted Prevention and Control Capacity - To coordinate and implement HAI prevention activities within the state, facilitate the state multidisciplinary advisory group on HAIs, and implement and report on progress of the state HAI plan, to develop and implement multi-facility prevention initiatives for HAIs. To strengthen surveillance and vaccine evaluation around vaccine preventable diseases such as meningococcal and pneumococcal diseases.

This program addresses the "Healthy People 2020" focus area(s) of Health

Communication and Health Information Technology, Healthcare-Associated Infections,

Immunizations and Infectious Diseases and Public Health Infrastructure

#### **Program Implementation**

#### **Recipient Activities**

Activities A-D are listed below, each with sub-activities and then suggested (but not exclusive) options for addressing the activity. Applicants may address one or more of the Activities.

Requirement for ALL Activities addressed: Recipients are required to track and report progress and impact through development and use of appropriate performance measures.

See Appendix A for guidance and required and suggested examples of performance measures for all Activities.

# Activity A: Epidemiology Capacity

- 1. Enhance outbreak investigation response and reporting:
  - Designate an epidemiologist with flexible responsibilities (i.e., multi-disease purpose 'ELC Epidemiologist').
  - Adopt use of standard investigative questionnaires (e.g., OutbreakNet *E. coli* O157 standard case interviews), data sharing tools and methods.
  - Foster collaboration among city, county, state and federal partners; participate in multi-state outbreak investigations; and assist local jurisdictions in the investigation of outbreaks that are large, complex or of national significance.
  - Increase epidemiology skills by participating in existing training or creating new training opportunities.

# 2. Upgrade and develop surveillance:

- Adapt workflows to accommodate increased volumes of ELR or syndromic reporting.
- Improve review of ongoing surveillance including more robust and varied analyses of surveillance data.
- o Facilitate coordination and exchange of surveillance data with other jurisdictions.
- o Better define burden of emerging infectious diseases.
- Develop and implement sentinel, syndromic and hospital-based (including emergency department) surveillance systems to better enhance early detection,

identify outbreaks and to support all-hazards situation awareness. [Note: syndromic surveillance systems should establish data sharing agreements in accordance with jurisdictional policy and legal authority and participate in the CDC BioSense data-sharing program.]

# 3. Evaluate epidemiologic public health practice:

- Evaluate the impact of vaccination and other prevention programs or interventions, which could include evaluation of vaccine effectiveness, disease burden, and barriers to implementation of preventive measures, as well as special surveillance activities.
- Periodically conduct evaluations of public health surveillance activities (e.g., reportable infectious disease surveillance, sentinel surveillance, syndromic surveillance) leading to data quality improvement and greater use of data for public health response.

# Activity B: Laboratory Capacity

- 1. Sustain and enhance laboratory diagnostic capacity:
  - Increase the number of labs utilizing modern techniques for diagnosis (e.g.
     RT-PCR). This may include purchase of equipment, supplies, reagents, etc.,
     necessary to expand capabilities and/or to improve laboratory throughput,
     efficiency, accuracy, etc.
  - Designate and train a laboratorian with flexible responsibilities (i.e., multidisease purpose 'ELC Laboratorian').

- Implement a plan for flexible use and acquisition of laboratory supplies that addresses changing and multi-disease purpose needs.
- Enhance skills and maintain pace with cutting-edge laboratory techniques by participating in existing training or creating new training opportunities.
- Participate fully in PulseNet including arranging for rapid transport of
  pathogens isolated from clinical specimens to the public health laboratory;
  rapid determination of molecular subtype of pathogens isolated from clinical
  specimens and implement next generation of molecular methods for standard
  serotyping of pathogens in PulseNet.
- Enhance public health laboratory capacity to detect and diagnose vaccine
  preventable and other respiratory diseases. Improve laboratory coordination and
  outreach:
  - Designate a laboratory 'connector' or liaison responsible for collaboration and coordination between state, clinical and hospital labs both within state/local jurisdiction and across jurisdictions.
  - Coordinate and strengthen connections between epidemiology and laboratory functions, at the state and local levels.

# Activity C: Health Information Systems Capacity

#### 1. Enhance Informatics Workforce:

 Designate an informatician (i.e. information systems specialist) with flexible responsibilities.

- Increase informatics and information technology skills to support surveillance,
   epidemiologic, and laboratory efforts and data interchange between health
   care and public health sector by participating in training or creating new
   training opportunities.
- Identify and dedicate personnel resources in IT, informatics, surveillance,
   and laboratory for advancing implementation of ELR.
- 2. Advance national implementation of ELR by improving your capacity to accept and work with incoming ELR messages in surveillance systems as well as to develop and implement capacity to handle messages according to MU standards.<sup>2</sup>
  - A. Large Reference/Clinical/ Labs to Health Department
    - Enhance the receipt of electronic laboratory reports from large reference or clinical laboratories by arranging for ELR from additional labs, transitioning to use of ONC MU standards for ELR, or both.
    - ii. Enable NEDSS-compliant surveillance systems to consume electronic lab reports from large reference/ clinical/ labs.
  - B. Hospital Laboratory to Public Health Agencies
    - i. Build capacity in your technical infrastructure to test (until successful) transmission of ONC-defined standards-based electronic laboratory reports from certified electronic health record technologies, defined by ONC to be a certified EHR system or EHR system module, such as a Laboratory

<sup>&</sup>lt;sup>2</sup> Funding for these enhancements should not interrupt existing ELR transmissions, even those not according to ONC standards. For example, while a plan to transition transmission/receipt of ELR from 2.3.1 to 2.5.1 is appropriate, this opportunity should not be interpreted as justification for stopping 2.3.1. without a plan for a reasonably seamless transition to the ONC standard. See also Footnote 1, above regarding MU standards.

Information Management System (LIMS), from eligible hospitals and other MU eligible providers<sup>3</sup>. As needed, use message validation tools provided by CDC for testing.

- ii. Accept production ELR messages for public health reporting from hospitals and other MU providers to state and local public health agencies.
- iii. Enable NEDSS-compliant case reporting systems to consume ONC-defined standard messages in order to process and analyze laboratory reports.

  Possible solutions include, in the short term, using a translation mapping tool to change incoming HL7 2.5.1 messages into HL7 2.3.1 for consumption in an electronic disease surveillance system and, in the longer term, enhance surveillance systems to consume and work with HL7 2.5.1 messages.

# C. LabID<sup>4</sup> Events to NHSN

Partner with two or more healthcare facilities within your jurisdiction's health information exchanges, electronic health record system (EHRs) vendors and/or healthcare associated infection software vendors to build an infrastructure that supports both the reporting of LabID Events to NHSN as well as the reporting of ELR to local or state public health, and to do so using existing implementation guides and common approaches.

i. Create an HL7 CDA<sup>5</sup> document for reporting of LabID events and associated denominators as specified by the implementation guide

<sup>&</sup>lt;sup>3</sup> For such ELR, meet the latest requirements of CMS & the Office of the National Coordinator for Health Information Technology (ONC) related to the Meaningful Use objective for the "Capability to submit electronic data on reportable (as required by state or local law) lab results to public health agencies".

<sup>&</sup>lt;sup>4</sup> The term LabID Event is used to convey the fact that these classes of HAIs are subject to identification through clinical microbiology laboratory testing. The National Healthcare Safety Network (NHSN) has developed standards based definitions for the reporting of LabID Events and their associated denominators to NHSN using HL7 balloted Clinical Document Architecture (CDA) documents.

- referenced above and validated at the following website (see http://www.alschulerassociates.com/validator/).
- ii. Consider creating an HL7 2.5.1 ELR message of reportable conditions to state or local public health department<sup>6</sup>.
- iii. Receipt and processing of a valid ELR message at a public health department.
- iv. Receipt and processing of a valid CDA document for a LabID Event and associated denominator by NHSN.
- v. Creation of shareable artifacts that may be used in replicating this effort in other locations with differing infrastructure and products.
- vi. Demonstrate successful transmission of electronic (automated) data submission to NHSN; data already captured for patient care electronically captured in the standardized format and transferred to NHSN.
- D. Public Health Laboratory to Epidemiology/Surveillance Component of Health

  Department
  - Upgrade LIMS system to enable sending electronic laboratory results for reportable conditions from public health laboratory to a NEDSS-compliant case reporting system using ONC-defined standards.
- E. Enhance technical infrastructure and surveillance information systems to accept and work with ELR, in particular, to successfully use an anticipated increased volume of laboratory reporting for reportable conditions.

<sup>&</sup>lt;sup>5</sup> See <a href="http://www.cdc.gov/nhsn/CDA">http://www.cdc.gov/nhsn/CDA</a> eSurveillance.html

<sup>&</sup>lt;sup>6</sup> The actual diseases reported will be determined by public health and the HAI conditions are to be determined jointly by CDC and the Public Health Department

F. Collaborate with CDC and other ELC recipients to advance and monitor implementation of ELR across the country, including transition to ELR that conforms to Meaningful Use standards. Participate, with CDC, in monitoring ELR implementation, through sites visits, phone calls, data validation efforts, etc., including developing a tally of ELR status by reporting laboratory. Note: ELR implementation is a national priority and this monitoring by all ELC recipients is required.

# 3. Establish and enhance syndromic surveillance

- A. Enhance early detection and situation awareness capability by establishing syndromic surveillance. Local and state syndromic surveillance practice should maintain consistency with community-consensus statements regarding the business process and technological requirements of the current state of public health syndromic surveillance practice. [ISDS Meaningful Use Workgroup, Final Recommendation: Core Processes and EHR Requirements for Syndromic Surveillance, www.syndromic.org/projects/meaningful-use
- B. Establish syndromic surveillance data sharing agreements with CDC in accordance with jurisdictional policy and legal authority and participate in the CDC BioSense data-sharing program.

<sup>&</sup>lt;sup>7</sup> To extent appropriate, utilize the the Core Business Model and EHR Requirements for Syndromic Surveillance (International Society for Disease Surveillance; <a href="http://syndromic.org">http://syndromic.org</a>) and accept electronic information using the latest version of the PHIN Syndromic Surveillance Messaging Guide, and CMS and ONC electronic transmission standards established for the Meaningful Use objective for the CMS Incentive Program for Electronic Health Records "Capability to submit electronic surveillance data to public health agencies." CMS & ONC regulations of January, 2011 are posted at

http://healthit.hhs.gov/portal/server.pt/community/healthit\_hhs\_gov\_meaningful\_use\_announcement/2996 or at http://edocket.access.gpo.gov/2010/pdf/2010-17207.pdf and

http://edocket.access.gpo.gov/2010/pdf/2010-17210.pdf respectively). Further information regarding changes to PHIN will be posted at (www.cdc.gov/osels/phitpo/mu/); please check the site regularly.

- C. Link local syndromic surveillance systems within jurisdiction and support local efforts to sustain syndromic surveillance practice, in cooperation with the BioSense Program.
- D. Update jurisdiction's information on the number of emergency departments participating in its syndromic surveillance network(s), estimated population under surveillance, and other information on the BioSense Program Redesign collaboration site (https://sites.google.com/site/biosenseredesign).

# Activity D: Targeted Prevention and Control Capacity

- 1. Healthcare-Associated Infections
  - A. State Healthcare-associated Infection (HAI) Prevention Infrastructure

    The purpose of this activity is to coordinate and implement HAI prevention
    activities within the state, facilitate the state multidisciplinary advisory group on
    HAIs, and implement and report on progress of the state HAI plan. Funding
    under this activity will ensure that state health departments can continue to make
    and monitor progress towards the HHS HAI Prevention targets. The HAI
    prevention activity supported by this project must be specified in the State HAI
    plan. Implement and monitor State HAI Prevention Efforts and progress towards
    targets specified in the state HAI action plan;
    - Coordinate activities of the HAI multidisciplinary advisory group to support the prevention effort.
    - o Assess needs within the state and work to address priority needs.

- Work with other patient safety collaborations within the state for HAI and other healthcare acquired conditions.
- Set a goal for the number of facilities to be enrolled in the prevention effort(s)
   and strive to meet that goal.
- Assess the impact of the prevention efforts through outcome measures which must include 1) number of facilities enrolled in the prevention activity and 2) at least one additional measure of each facility's prevention success.
- B. Prevention of Healthcare-associated Infections Across the Spectrum of Healthcare
  This activity builds upon successes from CDC's work with states on HAI
  prevention through the development and implementation of multi-facility
  prevention initiatives. Current efforts have demonstrated that many HAIs can be
  prevented through the implementation of best-practice recommendations for
  infection prevention. To meet national targets for HAI prevention, adherence to
  these recommendations must be expanded to all healthcare settings. Prevention
  activities funded under this cooperative agreement address critical needs for
  moving towards the elimination of HAIs in all healthcare settings and building
  upon specific advances made through investments in states. States can propose
  HAI prevention initiatives that meet the requirements in this activity. Prevention
  activities could include, but are not limited to:
  - Assess impact of the proposed prevention initiative(s), including number of infections prevented (*Required Activity if applying for Activity D.1.B*).

- Establish partnerships for the prevention of catheter associated urinary tract infections (CAUTI), central line associated blood stream infections (CLABSI), and surgical site infections (SSI).
- Prevent MDRO and Clostridium difficile infections across the spectrum of healthcare facilities.
- Collaborate with other state HAI and healthcare acquired condition prevention activities, as appropriate.

# 2. Vaccine Effectiveness (VE)

# A. Evaluation of Meningococcal Conjugate Vaccine

- Identify and serogroup all cases of meningococcal disease (defined by
  isolation from a normally sterile site or detection of meningococcal DNA on
  polymerase chain reaction) in the entire state or proposed catchment area in
  which enrollment will occur.
- o Transfer all isolates and specimens to CDC for confirmation of serogroup.
- Implement a protocol for enrolling cases and controls in a case-control
  investigation of vaccine effectiveness. This includes participating in
  conference calls and training sessions, collecting data including consenting
  participants, and transmitting data to CDC.
- Complete case investigations to determine demographic information, clinical
  presentation and outcome, vaccination status, type of vaccine, and date of
  vaccine for all cases of meningococcal disease, and vaccination status, type of
  vaccine, and date of vaccination for controls enrolled in the investigation.

- B. Assessing effectiveness of 13-valent pneumococcal conjugate vaccine
  - Collaborate with CDC, Emerging Infections Program (EIP) sites, and other
     ELC sites via conference calls to develop protocols that will include
     enrollment criteria, procedures for identifying appropriate controls and
     procedures for requesting participation from cases and controls.
  - Assist with developing and pilot testing instruments (e.g., questionnaires,
     chart abstract forms) and enrollment procedures to be used in the project.
  - Work with CDC to develop appropriate data systems that allow for secure collection and electronic transmission of data related to enrolled cases and controls.
  - Identify all cases of Invasive Pneumococcal Disease (IPD defined by isolation of pneumococcus from normally sterile body sites) in residents of the 2009 catchment areas (if conducting population-based surveillance) or occurring at sentinel sites (if using sentinel site surveillance). Identification of all cases is necessary to establish the baseline incidence of disease and to minimize any bias (especially toward more severe presentations) in case enrollment. Awardees are encouraged to consider expanding their 2009 surveillance areas for the purpose of increasing the potential number of cases enrolled, provided that such an expansion can maintain complete case ascertainment.
  - Attempt to obtain pneumococcal isolates from all cases for storage and subsequent shipment to existing CDC's Streptococcal Laboratory.

- Enroll cases (identified from ELC surveillance) and age-matched controls (identified by searching of birth certificates or another method mutually agreed upon with CDC), beginning after PCV-13 licensure and vaccine use among U.S. infants commences.
- Collect vaccine histories and information on potential risk factors for disease through interviews with parents of enrolled children and contact with their healthcare providers.
- Transmit to CDC data collected on cases and controls using data systems and timelines (see above).
- Collaborate with CDC to monitor enrollment, analyze data, interpret results,
   and prepare reports for presentation and publication.

### C. Strengthening pertussis reporting for vaccine evaluation

- O Utilize state-based pertussis reporting systems to conduct routine surveillance for pertussis with systematic case investigation and follow-up.
- Collect complete information on clinical course of infection, vaccination history (including information on vaccination dates, lot numbers and manufacturers), and other epidemiologic information of interest.
- Perform laboratory confirmation of *Bordetella pertussis* specimens, when available, at state public health laboratory.
- Utilize state immunization registries to obtain and/or verify vaccine history;
   link immunization registry data with pertussis surveillance data.
- Build and strengthen infrastructure to conduct evaluations of the U.S.
   pertussis vaccination program.

In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring.

#### **CDC** Activities

- 1. Provide subject matter expertise, consultation, and technical assistance to grantees in enhancing epidemiologic, laboratory, and information systems capacity for prevention and control of infectious diseases, including:
  - a. Provide technical assistance and subject matter expertise in the areas of electronic laboratory data exchange requirements, standards, and infrastructure, including:
    - Semi-monthly Nationwide Meaningful Use Calls with public health partners.
    - ii. CDC Meaningful Use Website that will include links to public health agency websites with MU contact information for use by vendors, eligible professionals, and eligible hospitals.
    - iii. Guidance for use of Public Health Information Network (PHIN)Messaging Guides: Electronic Laboratory Reporting,Immunizations, and Syndromic Surveillance.
    - iv. Tools for MU pre-test message validation.
    - v. Mapping tools for HL7 2.3.1 and HL7 2.5.1 translations for jurisdictions using Rhapsody integration engine technology.

- vi. Strategy for secure message transport of electronic messages to public health, which will include guidance and tools as necessary.
- vii. LOINC and SNOMED mapping to Reportable Conditions for ELR
- b. Provide technical assistance and subject matter expertise in the areas of syndromic surveillance practice and use of surveillance data for early detection and enhanced situation awareness during a public health response.
- 2. Assist in developing metrics, monitoring, and evaluating public health and program impacts, including progress in achieving the purpose of this program.
- 3. Provide national coordination of activities where appropriate.
- 4. Collaborate with recipients on specific activities to develop a sustainable infrastructure which may include site visits, webinars, and teleconferences.
- 5. Work with recipients to monitor the status and progress of ELR and electronic laboratory information exchange capacity of the hospital and commercial laboratories that participate in electronic laboratory information exchange with state and local public health agencies.
- 6. Provide local and state health departments access to regional (i.e., multistate) and national views of BioSense program data to enhance their situation awareness.
- 7. Provide local and state health departments with mechanism to provide input into the BioSense Program redesign (<a href="https://sites.google.com/site/biosenseredesign">https://sites.google.com/site/biosenseredesign</a>).

## **II. AWARD INFORMATION**

**Type of Award:** Cooperative Agreement. CDC substantial involvement in this program appears in the Activities Section above.

**Award Mechanism:** U50

Fiscal Year Funds: FY 2011

**Approximate Total Funding:** \$ 47,202,500 including approximately \$43,202,500 ACA funding and \$4,000,000 non-ACA funding. These amounts are estimates and include both direct and indirect costs. Approximate Funding Available by Activity:

Activity A- Epidemiology: \$7,500,000

Activity B - Laboratory: \$8,800,000

Activity C – Health Information Systems: \$21,700,000

Activity D.1.A – HAI Prevention Infrastructure: \$3,440,000

Activity D.1.B – HAI Prevention Collaboratives: \$4,500,000

Activity D.2.A – VE MCV: \$600,000

Activity D.2.B – VE PCV: \$262,500

Activity D.2.C – VE Pertussis: \$400,000

**Approximate Number of Awards: 58** 

**Approximate Average Award:** \$813,836 (This amount is for a 12-month budget period, and includes both direct and indirect costs.)

Activity A- Epidemiology: \$129,310 assuming 58 recipients

Activity B - Laboratory: \$151,724 assuming 58 recipients

Activity C – Health Information Systems: \$374,138 assuming 58 recipients. (This includes continuation activities and ELR and syndromic surveillance enhancements)

Activity D.1.A – HAI Prevention Infrastructure: \$66,154 assuming 52 recipients

Activity D.1.B – HAI Prevention Collaboratives: \$450,000 assuming 10 recipients

Activity D.2.A – VE MCV: \$75,000 assuming 8 recipients

Activity D.2.B – VE PCV: \$131,250 assuming 2 recipients

Activity D.2.C – VE Pertussis: \$100.000 assuming 4 recipients

Floor of Individual Award Range: None

Ceiling of Individual Award Range: None

**Anticipated Award Date:** June 15, 2011

**Budget Period Length:** 12 Months (August 1, 2011 to July 31, 2012)

**Project Period Length:** This FOA represents the second budget period continuation for

the 22-month Project Period that began September 30, 2010.

First Budget Period: September 30, 2010 – July 31, 2011

Second Budget Period: August 1, 2011 – July 31, 2012

### **III. ELIGIBILITY INFORMATION**

### **Eligible Applicants**

This FOA provides second budget period continuation with enhancement of ELC-ACA awards initiated in 2010 under FOA# CI10-1012. Therefore, eligible applicants are limited to the 58 current ELC ACA grantees (or their established bona fide agents) under FOA# CI10-1012, and are listed below:

Alabama, Alaska, Arizona, Arkansas, California, Chicago IL, Colorado,

Commonwealth of Puerto Rico, Connecticut, Delaware, District of Columbia,

Florida, Georgia, Hawaii, Houston TX, Idaho, Iowa, Illinois, Indiana, Kansas,

Kentucky, Los Angeles County CA, Louisiana, Maine, Maryland, Massachusetts,

Michigan, Minnesota, Missouri, Mississippi, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, New York City NY, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Philadelphia PA, Republic of Palau, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming.

A Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If applying as a bona fide agent of a state or local government, a legal, binding agreement from the state or local government as documentation of the status is required. Attach with "Other Attachment Forms" when submitting via <a href="www.grants.gov">www.grants.gov</a>.

Eligibility is further limited for the following activities:

Activities D.1.A and D.1.B. - Healthcare-Associated Infections – Eligibility is limited to only those grantees required to develop and submit an HAI plan as required by Congress. Eligible applicants thus are all 50 states, the District of Columbia and Puerto Rico. Eligibility is limited to these grantees because the intention is to continue support for specific activities previously supported in the 2009 American Recovery and Reinvestment Act (ARRA) HAI awards under FOA# CI07-70402ARRA09. The ARRA language specific to that ARRA HAI funding required that funding only go to "States."

Activity D.2.A - Evaluation of Meningococcal Conjugate Vaccine – Eligibility is limited to ELC grantees that received ARRA funds for Meningococcal vaccine (MCV) effectiveness projects under opportunity CI07-70403ARRA09. Eligible applicants thus are: Alabama, Arizona, California, Florida, Houston, Indiana, Iowa, Kansas, Maine, Massachusetts, Mississippi, New York City, North Carolina, Oklahoma, Philadelphia, South Carolina, Tennessee, Washington, and Wisconsin. Eligibility is limited to these grantees because the intention is to continue support for specific activities previously supported in the 2009 ARRA 317 Immunization awards for MCV under FOA# CI07-70403ARRA09.

Activity D.2.B - Assessing effectiveness of 13-valent pneumococcal conjugate vaccine Eligibility is limited to ELC grantees that received ARRA funds for Pneumococcal vaccine (PCV) effectiveness projects under opportunity CI07-70404ARRA09. Eligible applicants thus are: Los Angeles County, CA and Utah. Eligibility is limited to these grantees because the intention is to continue support for specific activities previously supported in the 2009 ARRA 317 Immunization awards for PCV under FOA# CI07-70404ARRA09.

## **Required Registrations**

**Central Contractor Registration and Universal Identifier Requirements** 

All applicant organizations **must obtain** a DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for

Federal grants or cooperative agreements. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services.

The recipient is required to have the original DUNS identifier to apply for additional funds.

An AOR should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an AOR should complete the **US D&B D-U-N-S Number Request Form** or contact Dun and Bradstreet by telephone directly at 1-866-705-5711 (toll-free) to obtain one. A DUNS number will be provided immediately by telephone at no charge. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a DUNS number.

Additionally, all applicant organizations must register in the Central Contractor Registry (CCR) and maintain their CCR registration with current information at all times during which it has an application under consideration for funding by CDC and, if an award is made, until a final financial report is submitted or the final payment is received, whichever is later. CCR is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the CCR internet site at <a href="https://www.ccr.gov">www.ccr.gov</a>.

If an award is granted, the grantee organization must notify potential sub-recipients that no organization may receive a sub-award under the grant unless the organization has provided its DUNS number to the grantee organization.

# **Cost Sharing or Matching**

Cost sharing or matching funds are not required for this program.

Maintenance of Effort

Maintenance of Effort is not required for this program.

# IV. Application and Submission Information

## Address to Request Application Package

Applicants must download the SF424 (R&R) application package associated with this funding opportunity from <u>Grants.gov</u>. If access to the Internet is not available or if the applicant encounters difficulty accessing the forms on-line, contact the HHS/CDC Procurement and Grants Office Technical Information Management Section (PGO TIMS) staff at (770) 488-2700 for further instruction. CDC Telecommunications for the hearing impaired or disable is available at: TTY 1-888-232-6348.

If the applicant encounters technical difficulties with Grants.gov, the applicant should contact Grants.gov Customer Service. The Grants.gov Contact Center is available 24 hours a day, 7 days a week, with the exception of all Federal Holidays. The Contact Center provides customer service to the applicant community. The extended hours will provide applicants support around the clock, ensuring the best possible customer service is received any time it is needed. You can reach the Grants.gov Support Center at 1-800-518-4726 or by email at <a href="mailto:support@grants.gov">support@grants.gov</a>. Submissions sent by email, fax, CD's or thumb drives of applications will not be accepted.

## **Content and Form of Application Submission**

Unless specifically indicated, this announcement requires submission of the following information:

A Project Abstract must be completed in the Grants.gov application forms. The Project

Abstract must contain a summary of the proposed activity suitable for dissemination to

the public. It should be a self-contained description of the project and should contain a

statement of objectives and methods to be employed. It should be informative to other

persons working in the same or related fields and insofar as possible understandable to a

technically literate lay reader. This abstract must not include any proprietary/confidential

information

A Project Narrative must be submitted with the application forms. The project narrative

must be uploaded in a PDF file format when submitting via Grants.gov. The narrative

must be submitted in the following format:

Maximum number of pages: 25. If your narrative exceeds the page limit, only the

first pages which are within the page limit will be reviewed.

Font size: 12 point unreduced, Times New Roman

Single spaced

Page margin size: One inch

Number all narrative pages; not to exceed the maximum number of pages.

Submit one narrative for each activity addressed (there are 8 Activities that could be

addressed:

A - Epidemiology

B - Laboratory

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C - Health Information Systems

D – Targeted Prevention and Control

D.1.A - HAI Prevention Infrastructure

D.1.B - HAI Prevention Initiatives

D.2.A - VE MCV

D.2.B - VE PCV

D.2.C - VE Pertussis

Each Activity narrative must include a progress report, new second budget period request, and budget detail/justification in the following format and order:

Progress Report for First Budget Period (9/30/10-7/31/11) – Activities A-C Only
For Activities funded in 2010, provide a detailed report on progress to-date.
Highlight significant successes or problems. Describe plans to address any
problems or challenges. Provide evidence of how ELC cooperative agreement
funds are being used to strengthen flexible epidemiology, laboratory and health
information systems practice and contributed to effective disease surveillance and
response by building these capacities (e.g., hiring flexible staff, conducting
outbreak investigations, expanding surveillance, improving laboratory
technology, etc.). Specifically address progress against each measure of
effectiveness (performance measure) included in your FY2010 ELC
Affordable Care Act proposal. CDC is tracking grantee progress against these

measures and this information will be considered in determining funding for the second budget period.

In addition to programmatic progress, specifically describe progress in spending the funds awarded for the first budget period (see also the requirements for submitting the Financial Status Report in paragraph 4) Budget, below). Describe progress in filling positions (i.e., number funded in the Sept 2010 award, number filled as of x date, number expected to be filled by July 31, 2011). Describe progress in implementing any contracts, major equipment purchases, etc.

Describe any challenges you may be experiencing in making expenditures and your plans to address them.

## 2. Second Budget Period Request (for 8/1/11 - 7/31/12)

#### A. Continuation of Activities A-C:

- Describe clear objectives and an operational plan for continuing Activities A-C for which you were funded in the first budget period. The Operational Plan must include a clear timeline for these activities over the full 12-month second budget period and identify specific persons/positions with responsibility for each objective and major activity.
- 2) Monitoring and Evaluation: Propose a plan for continued monitoring of progress with building and strengthening epidemiology, lab, and health information systems capacities. Include in this plan specific performance measures for epidemiology, laboratory and health information systems so

that progress and impact may be accounted for (see Appendix A for guidance and required and suggested performance measures).

# B. Monitoring Implementation of ELR:

Regardless of whether or not requesting funds in Activity C, provide a status update for your implementation of ELR by completing the following table and including it in your application:

Number and Percent of Labs using ELR in Grantee Jurisdiction		
Current Status as of: [provide date]		
Grantee:		
	Large Commercial	
	Labs ("Independent	
	Labs" per CLIA)	Hospital Labs
	Example data	
Total Number of Labs Reporting to the		
Jurisdiction	4	30
Labs Reporting via 2.3.1 Messaging Std	3	25
Labs in Testing Stage for Reporting via		
2.5.1 Messaging Std	1	1
Labs in Production for Reporting via 2.5.1		
Messaging Std	0	1
Labs Reporting electronically via format		
other than 2.3.1 or 2.5.1	0	3

C. Request for Enhancements in the Second Budget Period (new or expanded activities not previously funded in 2010)
 Please reference the "Budget Information and Justification" section below for the appropriate time periods to address for specific activities.

- 1) Background, Current Capacity, Need and Understanding
  - a) Describe, only as they relate to the specific activity enhancements

    being proposed, any capacity gaps and/or demographic and general

    disease burden characteristics of your jurisdiction, and provide details

    on unique challenges and characteristics of infectious diseases

    (including emerging infections) that your health department deals

    with.
  - b) Briefly introduce the activity enhancement being proposed and describe what the expected impact will be at the end of the project period, both in terms of outputs (i.e., process improvements, activities, etc.) and public health outcomes.

# 2) Operational Plan

- a) For activities selected, provide clear objectives and an operational plan for building and strengthening flexible epidemiology, laboratory, health information systems and/or prevention and control capacity.

  Include clear timelines and identify specific persons/positions responsible for each objective and major activity. Be specific, for example if addressing Activity C, by describing how newly implemented ELR capabilities would be used to meet MU criteria.
- b) Describe a clear plan, including designating staff, to enhance the integration of epidemiology, laboratory and health information systems components of the your health department and strengthen the

integration of ELC-funded categorical programs (e.g. influenza, NEDSS, foodborne diseases, etc.) through actions such as better communications and identifying and applying common resources, strategies, and tools, and applying them across program components. For Activity C - Health Information Systems, describe the capability or plan of your electronic disease surveillance system(s) to integrate ELR (specifically HL7 v2.5.1) with clinical and epidemiologic data including linking information from surveillance and clinician case reports with laboratory results case reports for the same case.

- c) Propose to work with CDC and other ELC recipients to monitor implementation of ELR, including providing periodic reporting of ELR status, participating through sites visits, phone calls, data validation efforts, etc., including tracking of ELR status by individual laboratory reporting to your jurisdiction.
- d) Describe organizational, fiscal, administrative, and/or programmatic challenges or limitations you expect to face and measures to overcome them associated with the implementation of your proposed enhanced activities. This plan should include a description of administrative and business strategy for how you will spend all awarded funds by the end of the second budget period. For example, how will you work through your jurisdiction's personnel system for hires, is there a strategy to use contractual mechanisms to more rapidly secure staff or services?

  Describe plans to assure adequate planning and that activities (e.g.,

hiring, contracting, procurement, collaborations, etc.) are implemented quickly with vigorous tracking and oversight to avoid delays and reduce the potential for unobligated funds remaining at the end of the budget and project period.

#### 3) Performance Measures

Provide a detailed plan for measuring and evaluating progress in the enhanced activities you have proposed for enhancements. Include in this plan specific performance measures for the enhancements and how those measures will be monitored and collected. For these quantitative measures, where appropriate, include a plan for providing complementary narrative that provides additional contextual details (e.g., how flexible staff resources were quickly deployed to address multi-state outbreaks). Measures identified should directly map to activities selected and described in your operational plan. Note that Health Information Systems activities have some required measures associated with them. See Appendix A for guidance as well as required and suggested measures for each Activity.

#### 4) Budget

Provide a fully detailed budget with narrative justification for the full second budget period (August 1, 2011 – July 31, 2012), except for the following activities where activities should be proposed and funds

requested only for the period of January 1, 2012 – July 31, 2012 (as these activities are currently supported under other ELC FOAs through December 31, 2011):

- Activity D.1.A State Healthcare-associated Infection (HAI)
   Prevention Infrastructure
- Activity D.2.A Evaluation of Meningococcal Conjugate Vaccine
- Activity D.2.B Assessing effectiveness of 13-valent pneumococcal conjugate vaccine

All budgets must be clearly broken out into the line-item categories specified in Form 424 (Salary, Fringe, Travel, Supplies, Equipment, Contractual, Other, and Indirect Costs). The budget must be consistent with stated program objectives and planned activities outlined in the operational plan. The budgets and budget justifications will not be counted in the narrative page limit. Be sure to consider and include requests for travel that may be necessary for proposed activities, including traveling up to 3 persons to a CDC-sponsored ELC grantee meeting sometime during the second budget period. Travel that is approved and funded by CDC will be considered a required activity.

Financial Status Report (SF 269):

As this is a continuation of your ELC-ACA award initiated in 2010 under FOA# CI10-1012, it is REQUIRED that you provide in the application an

submitting an interim Financial Status Report (FSR), form SF 269, for the current budget period that began September 30, 2010 (see also narrative reporting requirements in paragraph 1) Progress Report for First Budget Period, above). The form is available on the CDC internet at <a href="http://www.cdc.gov/od/pgo/forminfo.htm">http://www.cdc.gov/od/pgo/forminfo.htm</a>. The interim FSR must reflect all funds awarded in the current first budget period of this opportunity and estimated expenditures for the full 10-month first budget period, ending July 31, 2011. Therefore, the resulting unobligated balance (if any) will be an estimate of what will remain unobligated as of July 31, 2011.

Additional information may be included in the application appendices. The appendices must be uploaded to the "Other Attachments Form" of application package in Grants.gov. Note: appendices will not be counted toward the narrative page limit. This additional information includes:

- Curricula Vitae (include all CVs in one attachment)
- Organizational Chart
- Letters of Support (include all Letters of Support in one attachment, grouped or otherwise arranged to coincide with the separate Activity(ies) being addressed)
- Indirect cost rate agreements

Additional information submitted via Grants.gov must be uploaded in a PDF file format, and should be named:

Curricula vitae

Organizational Chart

Letters of Support

Indirect Cost Rate Agreement

No more than (5) appendices should be uploaded per application.

Additional requirements for additional documentation with the application are listed in

Section VI. Award Administration Information, subsection entitled "Administrative and

National Policy Requirements."

**Submission Dates and Times** 

This announcement is the definitive guide on application content, submission, and

deadline. It supersedes information provided in the application instructions. If the

application submission does not meet the deadline published herein, it will not be eligible

for review and the recipient will be notified the application did not meet the submission

requirements.

**Application Deadline Date:** May 2, 2011; 5:00pm Eastern Standard Time

**Explanation of Deadlines:** Application must be successfully submitted to Grants gov by

5:00pm Eastern Standard Time on the deadline date.

**Intergovernmental Review** 

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This is a continuation of a current grant program and so is not subject to

Intergovernmental Review of Federal Programs, as governed by Executive Order (EO)

12372.

## **Funding Restrictions**

Restrictions, which must be taken into account while writing the budget, are as follows:

- Recipients may not use funds for research.
- Recipients may not use funds for clinical care.
- Recipients may only expend funds for reasonable program purposes, including personnel, travel, supplies, and services, such as contractual.
- Awardees may not generally use HHS/CDC/ATSDR funding for the purchase of furniture or equipment. Any such proposed spending must be identified in the budget.
- The direct and primary recipient in a cooperative agreement program must
   perform a substantial role in carrying out project objectives and not merely serve
   as a conduit for an award to another party or provider who is ineligible.

The recipient can obtain guidance for completing a detailed justified budget on the CDC website, at the following Internet address:

http://www.cdc.gov/od/pgo/funding/budgetguide.htm.

## **Other Submission Requirements**

#### **Application Submission**

Submit the application electronically by using the forms and instructions posted for this funding opportunity on <a href="www.Grants.gov">www.Grants.gov</a>. If access to the Internet is not available or if the recipient encounters difficulty in accessing the forms on-line, contact the HHS/CDC Procurement and Grant Office Technical Information Management Section (PGO TIMS) staff at (770) 488-2700 for further instruction.

Note: Application submission is not concluded until successful completion of the validation process. After submission of your application package, recipients will receive a "submission receipt" email generated by Grants.gov. Grants.gov will then generate a second e-mail message to recipients which will either validate or reject their submitted application package. This validation process may take as long as two (2) business days. Recipients are strongly encouraged check the status of their application to ensure submission of their application package is complete and no submission errors exists. To guarantee that you comply with the application deadline published in the Funding Opportunity Announcement, recipients are also strongly encouraged to allocate additional days prior to the published deadline to file their application. Non-validated applications will not be accepted after the published application deadline date.

In the event that you do not receive a "validation" email within two (2) business days of application submission, please contact Grants.gov. Refer to the email message generated at the time of application submission for instructions on how to track your application or the Application User Guide, Version 3.0 page 57.

#### **Electronic Submission of Application:**

Applications must be submitted electronically at <a href="www.Grants.gov">www.Grants.gov</a>. Electronic applications will be considered as having met the deadline if the application has been successfully made available to CDC for processing from Grants.gov on the deadline date.

The application package can be downloaded from <a href="www.Grants.gov">www.Grants.gov</a>. Recipients can complete the application package off-line, and then upload and submit the application via the Grants.gov website. The recipient must submit all application attachments using a PDF file format when submitting via Grants.gov. Directions for creating PDF files can be found on the Grants.gov website. Use of file formats other than PDF may result in the file being unreadable by staff.

Applications submitted through Grants.gov (<a href="http://www.grants.gov">http://www.grants.gov</a>), are electronically time/date stamped and assigned a tracking number. The AOR will receive an e-mail notice of receipt when HHS/CDC receives the application. The tracking number serves to document submission and initiate the electronic validation process before the application is made available to CDC for processing.

If the recipient encounters technical difficulties with Grants.gov, the recipient should contact Grants.gov Customer Service. The Grants.gov Contact Center is available 24 hours a day, 7 days a week. The Contact Center provides customer service to the recipient community. The extended hours will provide recipients support around the clock, ensuring the best possible customer service is received any time it's needed. You

can reach the Grants.gov Support Center at 1-800-518-4726 or by email at <a href="mailto:support@grants.gov">support@grants.gov</a>. Submissions sent by e-mail, fax, CD's or thumb drives of applications will not be accepted.

Organizations that encounter technical difficulties in using <a href="www.Grants.gov">www.Grants.gov</a> to submit their application must attempt to overcome those difficulties by contacting the Grants.gov Support Center (1-800-518-4726, <a href="support@grants.gov">support@grants.gov</a>). After consulting with the Grants.gov Support Center, if the technical difficulties remain unresolved and electronic submission is not possible to meet the established deadline, organizations may submit a request prior to the application deadline by email to the Grants Management Specialist/Officer for permission to submit a paper application. An organization's request for permission must: (a) include the Grants.gov case number assigned to the inquiry, (b) describe the difficulties that prevent electronic submission and the efforts taken with the Grants.gov Support Center (c) be submitted to the Grants Management Specialist/Officer at least 3 calendar days prior to the application deadline. Paper applications submitted without prior approval will not be considered.

If a paper application is authorized, the recipient will receive instructions from PGO TIMS to submit the original and two hard copies of the application by mail or express delivery service.

# V. Application Review Information

Eligible recipients are required to provide measures of effectiveness (also referred to as "performance measures" throughout this FOA) that will demonstrate the accomplishment of the various identified objectives of this FOA. Measures of effectiveness must relate to the performance goals stated in the "Purpose" section of this announcement. Measures of effectiveness must be objective, quantitative and measure the intended outcome of the proposed program. The measures of effectiveness must be included in the application and will be an element of the evaluation of the submitted application. See Appendix A for guidelines as well as required and suggested performance measures.

## Criteria

Eligible recipients will be evaluated against the following criteria:

Background, Current Capacity, Need and Understanding (30 Points):

Extent to which applicant demonstrates a clear and comprehensive understanding of the challenges that this funding opportunity targets. Challenges include gaps in capacity for epidemiology, laboratory, surveillance, health information system, and prevention and control, general disease burden and unique infectious disease challenges. Extent to which applicant provides information on the population size, demographic characteristics, geographic distribution, racial/ethnic makeup, and health care delivery systems as they relate to their proposed new or expanded activities.

Does the applicant provide the requested information regarding the current status of ELR implementation in their jurisdiction? Does the applicant introduce the activity enhancement(s) being proposed and describe what the expected impact will be at the end of the project period, both in terms of outputs (i.e. process improvements, activities, etc.) and public health outcomes.

## Operational Plan (50 Points)

Extent to which the applicant identifies and proposes clear operational plan(s) for the various activities for which they are applying. Collectively, how well do the applicant's proposed activities address the overall program purpose of building flexible epidemiology, laboratory, health information systems and/or targeted prevention and control infrastructure and the objectives of the activities? Extent to which the applicant provides sufficient information on required staffing, management, supplies and equipment, training, space, and financial support needed to achieve optimal capacity. Extent to which the applicant demonstrates how new ELR data is or will be used for surveillance purposes. Does the applicant clearly demonstrate the intent to participate in monitoring (including periodic reporting of status) of national ELR implementation including through site visits, phone calls, data validation efforts, etc? How well does applicant's plan address overcoming barriers that may be encountered during implementation? Is the timeline for implementation of proposed activities clear and does it seem adequate? To what extent does the applicant demonstrate intent and potential to complete activities and expend funds within the timeframe of the Activity being addressed? Extent to which the

application describes a clear and high-quality plan, including, if appropriate, designating staff, to integrate elements of the ELC program which includes enhancing the integration of epidemiology, laboratory and health information systems components, and strengthening the integration of ELC-funded categorical programs (e.g. influenza, foodborne diseases, etc.) through actions such as better communications and identifying and applying common resources, strategies, and tools across program components. For health information systems, how well does applicant describe how their electronic disease surveillance system(s) will integrate ELR with clinical and epidemiologic data? How well do they describe their current capability to receive/route/consume/share ELR data using standard HL7 messages?

## Monitoring and Evaluation (20 Points):

Extent to which the applicant proposes clear plans that are consistent with the guidance in Appendix A of this FOA for monitoring progress - in processes and outcomes - of proposed activities and implementation. Does the applicant provide measures of impact and effectiveness (performance measures) that will demonstrate the accomplishment of the overall purpose of the funding opportunity and the objectives of the specific activity components (i.e., epidemiology, laboratory, surveillance, and health information systems capacity) so that impact and results from funding can be clearly discerned? Are the measures objective and quantitative and do they reflect activities proposed and described in the operational plan? Has the appropriate staff for various key activities been identified in order to effectively track implementation? Does the applicant provide a detailed description of how it will

compile and periodically update data on the status of their ELR and electronic laboratory information exchange capacity and performance?

Budget (SF 424A) and Budget Narrative (Reviewed, but not scored):

Are the itemized budget for conducting the project and justification reasonable and consistent with stated objectives and planned program activities? Is the required interim FSR included in the application?

If the applicant requests indirect costs in the budget, a copy of the indirect cost rate agreement is required. If the indirect cost rate is a provisional rate, the agreement should be less than 12 months of age. The indirect cost rate agreement should be uploaded as a PDF file with "Other Attachment Forms" when submitting via Grants.gov.

## **Review and Selection Process**

#### Review

Eligible applications will evaluated, scored, ranked, and selected for funding based on the review procedures described below.

All eligible applications will be initially reviewed for completeness by the Procurement and Grants Office (PGO) staff. In addition, eligible applications will be jointly reviewed for responsiveness by the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), the National Center for Immunization and Respiratory Diseases (NCIRD),

the Office of Surveillance, Epidemiology and Laboratory Services (OSELS), and PGO. Incomplete applications and applications that are non-responsive will not advance through the review process. Applicants will be notified the application did not meet eligibility and/or published submission requirements.

A structured review will be conducted to evaluate complete and responsive applications according to the criteria listed in the "V. Criteria" section above. The review will be conducted by program staff in the National Center for Zoonotic and Emerging Infectious Diseases (NCEZID), the National Center for Immunization and Respiratory Diseases (NCIRD), and the Office of Surveillance, Epidemiology and Laboratory Services (OSELS). As part of the review process, each applicant will receive a written Technical Review that summarizes the review findings regarding strengths, weaknesses, and recommendations.

#### **Selection**

All eligible and responsive applications will be selected for funding. Specific levels of funding for the different Activities will be based upon the structured review findings.

# VI. Award Administration Information

## **Award Notices**

Successful recipients will receive a Notice of Award (NoA) from the CDC Procurement and Grants Office. The NoA shall be the only binding, authorizing document between the recipient and CDC. The NoA will be signed by an authorized Grants Management Officer and e-mailed to the program director. A hard copy of the NoA will be mailed to the recipient fiscal officer identified in the application.

Unsuccessful recipients will receive notification of the results of the application review by mail.

#### **Administrative and National Policy Requirements**

Successful recipients must comply with the administrative requirements outlined in 45 Code of Federal Regulations (CFR) Part 74 or Part 92, as appropriate. For competing supplements, ARs remain in effect as published in the original announcement.

## **Competing Continuations**

- AR-7 Executive Order 12372
   AR-8 Public Health System Reporting Requirements
- AR-9 Paperwork Reduction Act Requirements
- AR-10 Smoke-Free Workplace Requirements

- AR-11 Healthy People 2020
- AR-12 Lobbying Restrictions

Additional information on the requirements can be found on the CDC Web site at the following Internet address: <a href="http://www.cdc.gov/od/pgo/funding/Addtl">http://www.cdc.gov/od/pgo/funding/Addtl</a> Reqmnts.htm.

For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address:

http://www.access.gpo.gov/nara/cfr/cfr-table-search.html

## Reporting

## **FFATA Requirements:**

Federal Funding Accountability And Transparency Act Of 2006 (FFATA): Public Law 109-282, the Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), requires full disclosure of all entities and organizations receiving Federal funds including grants, contracts, loans and other assistance and payments through a single publicly accessible Web site, <u>USASpending.gov</u>. The Web site includes information on each Federal financial assistance award and contract over \$25,000, including such information as:

- 1. The name of the entity receiving the award
- 2. The amount of the award
- 3. Information on the award including transaction type, funding agency, etc.

- 4. The location of the entity receiving the award
- 5. A unique identifier of the entity receiving the award; and
- 6. Names and compensation of highly-compensated officers (as applicable)

Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by recipients:

1) information on executive compensation when not already reported through the Central Contractor Registry; and 2) similar information on all sub-awards/subcontracts/ consortiums over \$25,000.

For the full text of the requirements under the <u>Federal Funding Accountability and Transparency Act of 2006</u>, please review the following website:

http://frwebgate.access.gpo.gov/cgi-

bin/getdoc.cgi?dbname=109 cong bills&docid=f:s2590enr.txt.pdf.

#### **Reporting Requirements Specific to this FOA:**

Reporting Requirements are outlined in the original FOA# CI10-1012 and your response to this FOA will count as the required Interim Progress Report (IPR) for the second budget period. Consistent with the requirements set forth in CI10-1012, the remaining reporting requirements are the Final Performance and Financial Status Reports, which are due no more than 90 days after the end of the project period (90 days after July 31, 2012). These reports must be submitted to the attention of the Grants Management Specialist listed in the Section VII below entitled "Agency Contacts."

## VII. Agency Contacts

CDC encourages inquiries concerning this announcement.

## For programmatic technical assistance and general inquiries, contact:

Alvin Shultz, ELC Program Coordinator

Division of Preparedness and Emerging Infections

National Center for Emerging and Zoonotic Infectious Diseases

Centers for Disease Control and Prevention

1600 Clifton Road, NE; Mailstop D-59

Atlanta, GA, 30333

Tel: 404-639-7028

Fax: 404-639-7880

Email: ashultz@cdc.gov

## For financial, grants management, budget assistance and general inquiries, contact:

De'Lisa Simpson, Grants Management Specialist

Department of Health and Human Services

CDC Procurement and Grants Office

2920 Brandywine Road, MS K-14

Atlanta, GA 30341

Telephone: 770.488.2905

E-mail: ion9@cdc.gov

For application submission questions, contact:

**Technical Information Management Section** 

Department of Health and Human Services

CDC Procurement and Grants Office

2920 Brandywine Road, MS E-14

Atlanta, GA 30341

Telephone: 770-488-2700

Email: pgotim@cdc.gov

CDC Telecommunications for the hearing impaired or disabled is available at: TTY 1-888-232-6348

# VIII. Other Information

Other CDC funding opportunity announcements can be found www.grants.gov.

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## **Appendix A – Performance Measures**

Accountability for public health investments under the Prevention and Public Health Fund (PPHF) of the Affordable Care Act is essential to demonstrate program impact and proper use of funds and for program management by the ELC program. All ELC grantees that received FY 2010 funding under the PPHF ELC announcement are expected and required to report on the metrics proposed for the activities which were funded. If measures do not provide evidence of progress, ELC requests that the grantee provide an explanation accompanying the measure with detail about why no progress was made (e.g., barriers, inappropriate measure, funds redirected towards alternative activity, etc.) Due to the flexible and general nature of activities under this FOA, recipients of funding will also have some flexibility regarding impact measures; however, a plan for program monitoring through measures of impact and effectiveness is required by all. These measures should quantitatively demonstrate improvement from the existing baseline level or establish a baseline where one currently does not exist; where appropriate, applicant should provide both numerator and denominator data so that change may be measured both by magnitude and percent. Examples below are provided as a guide only (except where noted otherwise in health information systems section); measures should be specific, quantitative, and relevant to activities for which you apply.

#### For Activity A: *Epidemiology Capacity*

- Hiring of epidemiology staff with FY 2010 ELC ACA funds awarded (number and date hired)
- Use of standard investigative questionnaires (e.g. OutbreakNet *E. coli* O157 standard case interviews), data sharing tools and methods (baseline usage and increase in use).
- Collaborations developed between city, county, state and federal partners for the purpose of outbreak investigation (baseline number and increase)
- Attend appropriate meetings and trainings to enhance knowledge related to public health threats (baseline number and increase)
- Timeliness of review of surveillance data (baseline time to review and decrease)

  [Note: Report timeliness of surveillance data review by the type of surveillance being conducted, e.g., syndromic, sentinel, or reportable disease surveillance.]
- Completeness of review of surveillance data quality [baseline completeness of information (number and percent of variables reviewed) and increase]. [Note: Report completeness of surveillance data elements by the type of surveillance being conducted, e.g., syndromic, sentinel, or reportable disease surveillance.]
- Analyses conducted using surveillance data (baseline number and increase)
- Coordination with other jurisdictions utilizing same surveillance systems (baseline number of jurisdictions and estimates of population coverage by jurisdiction and increase)
- Improvement in surveillance system performance relating to simplicity,
   flexibility, data quality, acceptability, sensitivity, predictive value positive,
   representativeness, timeliness and/or stability with metrics found in CDC's

<u>http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5013a1.htm</u> [Note: Report surveillance system evaluation findings by the type of surveillance being conducted, e.g., syndromic, sentinel, or reportable disease surveillance.]

- Evaluations of proven interventions (baseline number and change)

## For Activity B: Laboratory Capacity

- Hiring of laboratory staff with FY 2010 ELC ACA funds awarded (number and date hired)
- Improve sample throughput (baseline duration and decrease). Decreased time to reported results without decreasing sample integrity (baseline duration and decrease)
- Attend appropriate meetings and trainings to enhance knowledge related to public health threats. Use training platforms to expand knowledge related to outbreak investigation and surveillance (baseline number of trainings and increase)
- Collaborations with the public health epidemiologists to more effectively respond to public health threats (baseline count and increase)
- Laboratory techniques for which staff are proficient (baseline count and increase)

- Increase in number of outbreak clusters identified (baseline count and increase)
- Number of labs enrolled in grantees jurisdictional lab network (baseline count and increase)
- Number of staff with proficiency in a particular laboratory technique (baseline count and increase)
- Number of tests performed with new equipment procured through FY 2010 ELC
   ACA funding
- Number of new testing methods validated which were made possible with FY
   2010 ELC ACA funds

## For Activity C: Health Information Systems Capacity

#### Electronic Laboratory Reporting metrics

• Required Metric regardless whether or not applying for Activity C -- Number and percent of labs using ELR in jurisdiction (i.e. the number of labs reporting out of the applicable number of labs in your jurisdiction). ELR reporting labs should include large commercial labs and hospital labs and should include baseline numbers and change. See Section IV. Application and Submission Information, application narrative instructions paragraph 2.B., above, for the ELR implementation status table that is required to be submitted now with your application and that will be used to establish baseline status. During the course of the second budget period, CDC will work with recipients to further develop and implement tools for future periodic reporting such as the following working draft

table. DO NOT complete and submit below table with your application – this is only for illustrative and planning purposes for future ELR status monitoring/reporting under this cooperative agreement.

Reporting Jurisdiction:  (State/Tamitamy/Matronalitan Area)			
(State/Territory/Metropolitan Area)  Report Date: (enter date)			
Report Date.	Eligible	Independent	<b>Public Health</b>
	Hospitals	Labs	Lab
Estimated Number in	To be pre-populated	To be pre-populated	To be pre-populated
Jurisdiction	from CLIA data	from CLIA data	from CLIA data
Number (of Hospitals) that			
have contacted HD to start MU		N/A	N/A
testing			
Number in process MU testing		N/A	N/A
Number completed MU testing		N/A	N/A
<ul> <li>Number of hospitals successfully completing tests</li> </ul>		N/A	N/A
Number of hospitals that failed test		N/A	N/A
Number in the queue for on-			
boarding HL7 2.5.1 messaging			
Number actively participating			
in the on-boarding process for			
moving to production sending			
HL7 2.5.1			
Number not moving to		N/A	N/A
production and why? ♦			
Number in ongoing production			
sending to HD in HL7 2.5.1 △			
[with follow up submissions -			
as defined by CMS]			
Number currently in			
production with ELR in a			
format other than 2.5.1			

Δ Per hospital, provide a list of reportable conditions being sent. on a separate document.

<sup>♦</sup> Per hospital, list the reason on a separate document

#### Additional Measures:

- Hiring of informatics staff with FY 2010 ELC ACA funds awarded (number and date hired)
- For jurisdictions receiving electronic laboratory reports, measure the timeliness of reporting and specify the type of dates being compared (e.g., difference between date of specimen collection and date of receipt of laboratory result at state or local health department) (baseline and change).
- Increase in LIMS modules (e.g. clinical microbiology, serology, virology, etc.)
- Increase in informatics trainings developed and/or attended
- Increase in number of external partners (e.g. CDC, other state labs, private laboratories, hospitals, etc.) involved in electronic data exchange with health department. (Note: Specify type of electronic data exchange (e.g., ELR, syndromic surveillance, or reportable condition reporting) by partner.)
- Increase in frequency and type of automatic laboratory data interchange with public health epidemiology programs.

## Syndromic Surveillance Metrics

- Required Metric if applying for syndromic surveillance activity:
  - Baseline data for number and types of health care providers currently participating in syndromic surveillance;
  - o Estimates of population coverage;
  - o Conditions or syndromes under surveillance;

- Whether or not data are reported in aggregate format or for individual patient encounters.
- Increase the coverage of all-hazards ED-based syndromic surveillance. [Note: At minimum, report coverage as number of emergency departments in your jurisdiction participating in syndromic surveillance (numerator) and total number of emergency departments in your jurisdiction (denominator). If estimates of ED patient population both those under surveillance in participating sites (numerator) and the total number of ED visits in your jurisdiction (denominator) per time period -- are available, please report that as well. Specify time period and geographic unit of analysis (i.e., state, city, county) for the reported data.]
- Increase the timeliness of all-hazards ED-based syndromic surveillance.
  Determine the average timeliness of syndromic surveillance reporting by determining the mean of the lag times between date and time of day of the patient encounter and date and time of day of receipt of a syndromic surveillance case report by the public health agency.
- At least bi-annual updates of the jurisdiction's information on the number of
  emergency departments (or other clinical settings, specified by type) participating
  in its syndromic surveillance network(s), estimated population under surveillance,
  and other network information on the BioSense Program Redesign collaboration
  site (https://sites,google.com/site/biosenseredesign).

### For Activity D: Targeted Prevention and Control Activities

#### Healthcare-Associated Infections

- Maintenance of HAI state coordinator position (Activity D.1.A)
- While states have the ability to propose prevention activities for HAI targets of
  their choosing, all recipients of these funds must provide a proposal to assess
  impact as an outcome measure of infections prevented. Proposals that do not
  include methods for assessing the number of infections prevented will not be
  considered. (Activity D.1.B)
- For proposals on projects in long term care and hemodialysis, recipients must propose a way to measure or estimate the number of potential hospitalizations avoided. Proposals that do not include these measures will not be considered. (Activity D.1.B)

## Vaccine Effectiveness

## Evaluation of Meningococcal Conjugate Vaccine

- Number of cases of meningococcal disease identified
- Number (%) of cases enrolled
- Number (%) of controls enrolled
- Number of complete case/control sets enrolled.

## Assessing effectiveness of 13-valent pneumococcal conjugate vaccine

- Participation on conference calls related to this activity, i.e., ≥1 site participant per call.
- Proportion of eligible cases enrolled in the evaluation.
- Proportion of enrolled cases from which isolates are forwarded for serotyping.

 Proportion of enrolled cases and controls with provider verified vaccination status reported

# Strengthening pertussis reporting for vaccine evaluation

- Participation on conference calls related to this activity.
- Completeness of case report form data (e.g., clinical information, vaccine history, laboratory testing, etc.).
- Proportion of pertussis specimens available at State Public Health Laboratory.